

## **Agenda:**

### **Overview of FDA activities on SPL indexing**

FDA has completed an initial indexing of established pharmacologic class for active ingredients in CDER-reviewed applications. The results are here:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162549.htm>

Note: scroll down page and click on "FDA Pharmacologic Classes"

#### **Questions from attendees about pharmacologic class indexing:**

Q: specificity for one vs generality for another (see beta blocker examples) – intentional?

A: most likely this was intentional. Looking at scientific relevance

Q: multiple drugs in one class – did you lean to the safe side (e.g., beta-blocker).

A: only based on scientific research, not ‘presumption’ based on class

Q: Was the coding done so – if there was uncertainty about co-prescribed drugs – downstream systems would be more prone to over-warning vs under-warning?

A: Looking at scientific relevance

Q: Questions about assigned term(s): Address to [SEALD@fda.hhs.gov](mailto:SEALD@fda.hhs.gov)

ACTION: Determination of where to send more errors, discussion/questioning; Laurie Burke will respond with more information

Q: What about active ingredients not yet in the table?

A: Table will be updated frequently (e.g., monthly).

Q: Scope of indication – CDER, CBER

A: CBER is now looking into established pharmacologic class. CDER and CBER are both beginning to work on indexing indications. [I cannot confirm this—maybe Randy can.]

FDA now considering the next areas of indexing: intent of use, drug interactions or adverse reactions. Indications are definitely the next step. The other areas also need examination.

ACTION FOR ALL: FDA is looking for feedback on indexing priorities and on methodology, other factors related to indexing, how to approach the coding (level of coding, degree of specificity). For instance, just by picking condition, you can go in many different areas of coding.

COMMENT: FDA should begin working with e-prescribing systems, clinical decision support systems, those involved in patient record coding will be very important. Compendia suppliers might be a good source (e.g., NCPDP). Another suggestion – FDA could reach out to the Institute of Medicine.

Q: When a decision was made to go forward, in the guidance there was a suggestion about putting a listing in the Federal Register. Is the FDA planning to put such a notice in the Federal Register?

A: Current Guidance isn't clear – it lists several options for obtaining feedback.

COMMENT: Worry about current indexing effort – is the effort intended to be displayed on DailyMed? Or separately, as for pharmacological class?

Two fields for indication: Intent of Use, actual Indication (from SNOMED)

Indications – term and code from SNOMED CT

Intent of Use: three categories

#### Questions about indication:

Q: Limitations of use per indication, Contraindication per indication – is this a correct interpretation? Or, would you only want to index contraindications that are explicitly stated in the labeling. Should contraindications be spelled out to enable indication coding

A: Where the indexing is drawn from would speak to how severe the problem would be (frequency or severity)

Q: Dialog with those coding patient records – has this been done?

A: Not yet. Good suggestion.

Q: Label contains details about intent of use, but not a specific condition (e.g., anesthesia)

A: This is still up for discussion (how to code, when to code)

Q: Are you focusing only on the medical condition? Or extend to limitations of use, pre-conditions, etc.

A: We really want to focus (right now) on medical condition.

Q: Relating back to pharmacologic class discussion around beta-blockers (level of granularity), are you looking for similar feedback for indication?

A: Yes. We often have a high level of specificity around indication within the Review Division. Indexing may need to be at a higher level.

Q: Are there already-defined use cases?

A: FDA is looking for use cases. Really important that the use case of the clinician was first and foremost, as the established pharmacologic class needs to show up in the Highlights section. For indication, that's not as clear.

Assessment is complicated: We know from talking about this internally at FDA – such a difference in issues and concerns. There is a level of knowledge needed about SPL to understand some of the issues and concerns.

Possible use cases:

Q: Data model – could it be extended for use-case specific indications

A: Level of specificity that we're going to aim for (cds systems, etc.). There could be multiple use cases that would require indexing at different levels.

Going forward:

- The FDA's provided indexing could be linked to other document types – such as public advisories.
- Sponsor files remain intact – indexing file would be separate from them
- NLM (RxNorm) and VA (NDF-RT) also exploring ways to link these all together.

ACTION FOR ALL: FDA is looking for feedback on priorities for indexing and methodology, other factors related to indexing, how to approach the coding (level of coding, degree of specificity). For instance, just by picking condition, you can go in many different areas of coding.

Any suggestions about how to best make the information available? For indications and other things, we are definitely interested in suggestions about how best to make the information available. Pharmacologic class (MoA, PE, Chemical Structure) are available on the NDF-RT. The NDF-RT could be another location for this type of information.

Comments/ feedback on which of the various elements that support the Indication model should be indexed next.